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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,070	12/21/2001	William P. Van Antwerp	PD-0340 DIV	4432
23608	7590	05/05/2006	EXAMINER	
MEDTRONIC MINIMED INC. 18000 DEVONSHIRE STREET NORTHRIDGE, CA 91325-1219			STIGELL, THEODORE J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/028,070	Applicant(s) VAN ANTWERP ET AL.	
	Examiner Theodore J. Stigell	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

The Examiner acknowledges that the claims drawn to Group I (1-16) were previously cancelled by virtue of the Preliminary Amendment filed on December 21, 2001. Claims 17-24 have been examined in the instant Office Action.

Information Disclosure Statement

The information disclosure statement filed 12/21/2001 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. It is not clear to the Examiner what the phrase “, and associated with placing...the site housing material.” is referring to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-21 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Orth et al. (5,324,518). See Figure 2 and the respective portions of the specification. Orth discloses a reusable infusion site (20) for use with a replaceable infusion catheter for infusing a fluid into the body of a user the site comprising a site housing material (24) formed to have an interior cavity with an opening and a conduit (70,72) that is connected to the opening to provide access to the interior cavity, wherein the site housing material is selected to promote tissue ingrowth and vascularization and be free of tissue ingress, wherein the site housing material permits the fluid to pass through the material from the cavity to the body and the conduit has a predetermined length to prevent trauma and encapsulation and associated with placing the replaceable infusion catheter in the interior cavity of the site housing, and from interfering with tissue ingrowth and vascularization, wherein the conduit is at least 5 mm, wherein the site housing material has a porosity between 2 and 25 microns, wherein the site housing material can be placed in sub-dermal or inter-peritoneal tissue, wherein the site housing

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can last for two or more infusions, and wherein the site housing material passes insulin and wherein the replaceable infusion catheter is an insulin compatible delivery catheter.

Claims 17-21 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ash et al. (4,402,694). See Figure 1 and the respective portions of the specification. Ash discloses a reusable infusion site (15) for use with a replaceable infusion catheter (35) for infusing a fluid into the body of a user the site comprising a site housing material (15) formed to have an interior cavity with an opening and a conduit (14) that is connected to the opening to provide access to the interior cavity, wherein the site housing material is selected to promote tissue ingrowth and vascularization and be free of tissue ingress, wherein the site housing material permits the fluid to pass through the material from the cavity to the body and the conduit has a predetermined length to prevent trauma and encapsulation and associated with placing the replaceable infusion catheter in the interior cavity of the site housing, and from interfering with tissue ingrowth and vascularization, wherein the conduit is at least 5 mm, wherein the site housing material has a porosity between 2 and 25 microns, wherein the site housing material can be placed in sub-dermal or inter-peritoneal tissue, wherein the site housing can last for two or more infusions, and wherein the site housing material passes insulin and wherein the replaceable infusion catheter is an insulin compatible delivery catheter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Orth et al. (5,324,518) or Ash et al. (4,402,694). Orth and Ash disclose the invention as substantially claimed but do not disclose to make the site housing material from Teflon or Dacron. However, the Applicant has not disclosed that the use of these materials is

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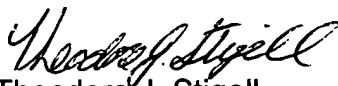
for any purpose or solves any stated problem. Therefore, the use of Teflon and Dacron is deemed to be a matter of design choice that fails to patentably distinguish the Applicant's invention from the cited references.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Theodore J. Stigell


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